K100915

# 510(k) Summary and Certification

*1. Submitter's Name / Contact Person*

**Submitted by:**
Hutchinson Technology, Inc.
BioMeasurement Division
40 West Highland Park NE
Hutchinson, MN 55350

**Contact Person**
Colin M McGraw
Operations Manager
Tel: (320) 587-1272
Fax: (320) 587-1671

APR 30 2010

Summary Date: March 30, 2010

*2. General Information*

| | |
|---|---|
| **Proprietary Name** | **InSpectra™** $StO_2$ Tissue Oxygenation Monitor, Model 650 |
| **Common / Usual Name** | Tissue Oximeter |
| **Classification Name** | Oximeter |
| **Class** | II |
| **Product Code** | 74MUD |
| **CFR Reference** | 21CFR§870.2700 |
| **Identification of Equivalent Devices** | Hutchinson Technology, Inc. – **InSpectra™** $StO_2$ Tissue Oxygenation Monitor, Model 650 (K061619)<br>Hutchinson Technology, Inc. – **InSpectra™** Tissue Spectrometer System, Model 325 (K053618) |

*3. Device Description*

The **InSpectra™** $StO_2$ Tissue Oxygenation Monitor ('Model 650'), is a lightweight and transportable system that is designed to estimate the percent oxygen saturation of hemoglobin in a volume of tissue ($StO_2$). The Model 650 is composed of the following components:

**InSpectra™** $StO_2$ Tissue Oxygenation Monitor. The **InSpectra™** $StO_2$ Monitor contains an LCD screen, a microcontroller, cooling fan, back-up battery, and internal software. The monitor has an internal lithium ion battery and two external data ports. It is equipped with an adjustable C-clamp for attachment to an IV pole.

**InSpectra™** $StO_2$ Cable, which can be removed from the monitor and replaced, contains light detection circuitry, a microcontroller, one set of optical fibers to transmit light to the tissue, and a second set of optical fibers that receive light from the tissue and return it to a photosensitive detector and internal software.

The **InSpectra™** $StO_2$ Sensor. The single-use **InSpectra™** $StO_2$ Sensor, when connected to the **InSpectra™** $StO_2$ Cable, conducts the optical signal to the patient and back to the monitor. The sensor has a shield to protect the measurement from ambient light interference, a reinforced cable to protect the optical fibers, and an adhesive surface to facilitate attachment of the sensor to the patient for continuous monitoring.

*4. Intended Use*

Hutchinson Technology Incorporated's **InSpectra™** $StO_2$Tissue Oxygenation Monitor is intended for use as a non-invasive monitoring system that measures an approximated value of percent hemoglobin oxygen saturation in tissue ($StO_2$).

The **InSpectra™** $StO_2$Tissue Oxygenation Monitor is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

*5. Technological Characteristics*

The **InSpectra™** $StO_2$Tissue Oxygenation Monitor has the same basic technological characteristics as the predicate device(s) based on near-infrared technology. The modified device is equivalent in terms of design, functionality, principles of operation, performance specifications and intended use. The labeling clarifications raise no new technological issues.

*6. Substantial Equivalence Rationale*

Based on design, technological characteristics, and intended use, HTI believes that the Model 650 with labeling clarifications is substantially equivalent to the predicate devices currently marketed under 510(k) K061619 and K053618.

*7. Test Conclusions*

HTI conducted a risk analysis to support the labeling clarification and concluded that no new testing was required. Based on information supplied in the 510(k), we conclude that the subject device with labeling clarifications is safe, effective, and substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Hutchinson Technology, Inc.
c/o Mr. Colin McGraw
Biomeasurement Division
40 West Highland Park Dr., NE
Hutchinson, MN 55350

APR 30 2010

Re: K100915
Device Name: InSpectra™ StO2 Tissue Oxygenation Monitor, Model 650
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II (Two)
Product Code: MUD
Dated: March 30, 2010
Received: April 1, 2010

Dear Mr. McGraw:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100915

Device Name:

**InSpectra™** $StO_2$ Tissue Oxygenation Monitor, Model 650

Indications for Use:

Hutchinson Technology Incorporated's **InSpectra™** $StO_2$ Tissue Oxygenation Monitor is intended for use as a non-invasive monitoring system that measures an approximated value of percent hemoglobin oxygen saturation in tissue ($StO_2$).

The **InSpectra™** $StO_2$ Tissue Oxygenation Monitor is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100915